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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,165	12/20/2001	William H. Fleming	899-61868	6245
24197	7590	01/30/2004	EXAMINER	
KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			LANKFORD JR, LEON B	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/019,165

Applicant(s)

FLEMING, WILLIAM H.

Examiner

L Blaine Lankford

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 27-46 is/are pending in the application.
- 4a) Of the above claim(s) 11-22, 27-36 and 41-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 37-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of group II is acknowledged. The traversal is on the ground(s) that the restriction is improper. This is not found persuasive because the holding of unity of invention in the PCT is not binding to the national stage application and for the reasons set forth in the previous action.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10 and 37-40 are examined on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 & 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Angelini (EP 0730849 A2) and Sachs(5876708) .

Angelini teaches vascular grafts and Sachs teaches a variety of vascular and organ transplants. All of the claimed types of vascular tissue transplantations (as defined in the specification) claimed by applicant are notoriously old and well known in the art, e.g. organ transplants, heterologous vein transplants, autologous bypasses,

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etc. Applicant would not appear to dispute this fact. The prior art does not teach that hematopoiesis is enhanced by the transplants however such a result would necessarily be inherent to the transplantations taught in the art because the method and materials claimed by applicant are the same as taught by the prior art. The claimed effect is apparently a previously unrecognized result of a known method and therefore the method is anticipated by the methods of the prior art.

The references anticipate the claimed invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 and 37-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the enhancing of hematopoiesis in a patient by the transplantation of vascular tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant has not enabled a method of transplanting any and all vascular tissue in such a way that hematopoiesis is enhanced. It would require undue experimentation to determine what sort of vascular tissue (particularly given the breadth of applicant's

definition of vascular tissue). In the instant case it is highly improbable that any vascular tissue will more likely than not perform in the manner disclosed and the instant specification does not provide the guidance needed to find other tissue with the desired functional property with any reasonable expectation that such tissue will be found.

The breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not without actually making and testing them then the instant application does not support the breadth of the claims.

Critical elements which are needed for the instant process, i.e. necessary components of the tissue, appear to have been excluded from the claims and the instant claims are not enabled.


Claims 1-10 and 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements.

It would appear that there are elements besides just "vascular tissue" which must necessarily be included in/with the tissue in order to enhance hematopoiesis. From reading applicant's specification, it does not appear that vascular tissue alone will accomplish the claimed desired effect.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to L Blaine Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



L. Blaine Lankford  
Primary Examiner  
Art Unit 1651

LBL